(19) Europäisches Patentamt
European Patent Office
Office européen des brevets

(11) EP 0 846 472 A1

(12) EUROPEAN PATENT APPLICATION

(43) Date of publication:
10.06.1998 Bulletin 1998/24

(51) Int Cl.[6]: **A61M 25/10**

(21) Application number: **97309826.2**

(22) Date of filing: **05.12.1997**

(84) Designated Contracting States:
AT BE CH DE DK ES FI FR GB GR IE IT LI LU MC NL PT SE
Designated Extension States:
AL LT LV MK RO SI

(30) Priority: **09.12.1996 US 762637**

(71) Applicant: **MEDTRONIC, INC.**
Minneapolis, Minnesota 55432 (US)

(72) Inventors:
- **Schwab, Sharon**
  San Diego, California 92117 (US)
- **Le, Leslie**
  San Diego, California 92111 (US)
- **Amores, Maria D.**
  San Diego, California 92114 (US)
- **Minas, Maritess**
  San Diego, California 92139 (US)

(74) Representative: **Hughes, Andrea Michelle**
Frank B. Dehn & Co.,
European Patent Attorneys,
179 Queen Victoria Street
London EC4V 4EL (GB)

(54) Catheter balloon bonding stopper

(57) A medical catheter comprising a catheter shaft 80 defining an inflation lumen 25 and a guidewire shaft 70 defining a guidewire lumen 65. The guidewire shaft is coaxial with the catheter shaft and runs longitudinally through the catheter shaft extending distally beyond the distal end of the catheter shaft. The catheter has an inflatable balloon 35 having a proximal tail and a distal tail. The proximal tail is mounted at the distal end of the catheter shaft, the distal tail is mounted on the guidewire shaft. The balloon is in fluid communication with the inflation lumen. A stopper means 30,50 is sealingly affixed between the outer diameter of the guidewire shaft and the inner diameter of the proximal and/or distal tail. The distal and proximal stopper means 50,30 are annular in shape and are in length shorter than the balloon tail and are of uniform circumferential thickness. An adhesive 5,10 seals a portion of the tails to the catheter shaft 80.

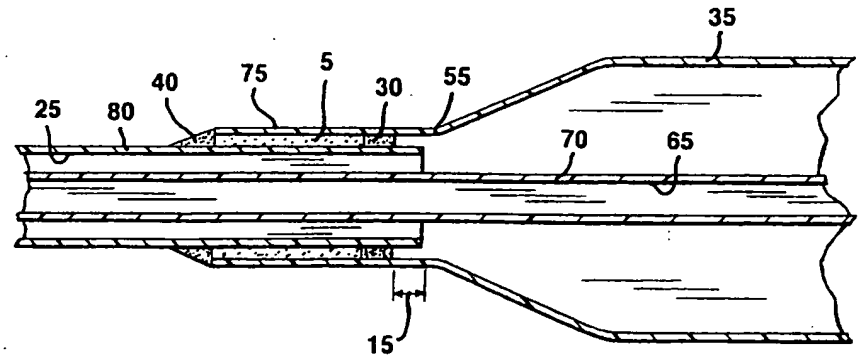

FIG.1

EP 0 846 472 A1

Description

The present invention relates to angioplasty catheters, and more particularly, to a catheter balloon bond at the balloon proximal or distal end.

One of the therapeutic procedures applicable to the present invention is known as percutaneous transluminal coronary angioplasty (PTCA). This procedure can be used, for example, to reduce arterial build-up of cholesterol fats or atherosclerotic plaque. Typically a first guidewire of about 0.95mm (.038 inches) in diameter is steered through the vascular system to the site of therapy. A guiding catheter, for example, can then be advanced over the first guidewire to a point just proximal of the stenosis. The first guidewire is then removed. A balloon catheter on a smaller 0.35mm (.014 inch) diameter second guidewire is advanced within the guiding catheter to a point just proximal of the stenosis. The second guidewire is advanced into the stenosis, followed by the balloon on the distal end of the catheter. The balloon is inflated causing the site of the stenosis to widen. The original catheter can then be withdrawn and a catheter of a different size or another device such as an atherectomy device can be inserted.

Conventional angioplasty balloons fall into high, medium, and low pressure ranges. Low pressure balloons are those that have burst pressures below 6.1 x 10^5 Pascals (6 atmospheres). Medium pressure balloons are those that have burst pressures between 6.1 x 10^5 and 1.2 x 10^6 Pa (6 and 12 atm). High pressure balloons are those that have burst pressures above 1.2 x 10^6 Pa (12 atm). Burst pressure is determined by such factors as wall thickness and tensile strength, for example.

High pressure balloons are desirable because they have the ability to exert more force and crack hard lesions. High pressure balloons are also useful in stent deployment. A biocompatible metal stent props open blocked coronary arteries, keeping them from reclosing after balloon angioplasty. A balloon of appropriate size and pressure is first used to open the lesion. The process is repeated with a stent crimped on a high pressure balloon. The stent is deployed when the balloon is inflated. A high pressure balloon is useful for stent deployment because the stent must be forced against the artery's interior wall so that it will fully expand thereby precluding the ends of the stent from hanging down into the channel encouraging the formation of thrombus.

Many bonding techniques for bonding a balloon to a shaft, as for example, laser welding or heat bonding, require thermally similar materials. Adhesive bonds are useful when bonding materials that have different thermal characteristics. For example, a polyethylene terephthalate (PET) high pressure balloon cannot be heat or laser bonded to a polyethylene (PE) shaft because their melt points are not compatible. For performance reasons a shaft and balloon made of thermally dissimilar materials which cannot be heat or laser bonded to the balloon may be desirable. The advantage of adhesive bonds is a common bonding method for thermally dissimilar materials.

U.S.P.N. 4,406,653 to Nunez discloses a method and apparatus for a catheter-balloon assembly wherein the catheter balloon is mounted on the catheter by means of adhesive and, in the preferred mode, an annular internal rib protrusion of the catheter balloon is provided for forming a sharply defined boundary of adhesive thereby aiding in the even and symmetrical inflation of the catheter balloon.

Concentric bonding of coaxial shafts often results in eccentric, inconsistent bonds which can result in bond failure. Some devices use a manufacturing fixture to align the coaxial shafts. External fixtures typically hold the outer diameters of the two shafts and insert one into the other. Shaft diameter, wall thickness and concentricity variation can still result in inconsistent bonds.

Adhesives may wick past the end of the shaft into an unintended lumen. To remedy this some adhesive bonds are lengthened to minimize the chance of the adhesive wicking past the end of the lumen. The presence of an elongate stiff section of adhesive can be a disadvantage with respect to catheter flexibility and trackability. The shorter the bond the easier it is to negotiate a tortuous path. What is needed is a balloon bond which minimizes bond length and thereby optimizes flexibility as well as withstands internal pressure of at least 3.4MPa (500 psi) without leaking or rupturing and which is relatively easy, consistent and reliable to manufacture.

The above features and advantages of the present invention, as well as others, are accomplished by providing, according to one aspect a medical catheter comprising:

a catheter shaft defining an inflation lumen, the catheter shaft having an inner diameter, outer diameter, proximal end and distal end;

a guidewire shaft defining a guidewire lumen, the guidewire shaft being coaxial with the catheter shaft, the guidewire shaft running longitudinally through the catheter shaft and extending distally beyond the distal end of the catheter shaft;

an inflatable balloon having a proximal tail having an inner diameter, a distal tail having an inner diameter, the proximal tail being mounted on to the distal end of the catheter shaft, the distal tail being mounted on to the guidewire shaft, the balloon being in fluid communication with the inflation lumen;

a stopper means sealingly affixed between the outer diameter of the catheter shaft and the inner diameter of the proximal tail, the stopper means being annular in shape and being in length shorter than the proximal tail and being of uniform circumferential thickness; and

an adhesive sealing a portion of the proximal tail, which is proximal to the stopper means, to the cath-

eter shaft.

According to another aspect, there is provided a medical catheter comprising:

a catheter shaft defining an inflation lumen, the catheter shaft having an inner diameter, outer diameter, proximal end and distal end;
a guidewire shaft defining a guidewire lumen, the guidewire shaft being coaxial with the catheter shaft, the guidewire shaft running longitudinally through the catheter shaft and extending distally beyond the distal end of the catheter shaft;
an inflatable balloon having a proximal tail having an inner diameter, a distal tail having an inner diameter, the proximal tail being mounted at the distal end of the catheter shaft, the distal tail being mounted on the guidewire shaft, the balloon being in fluid communication with the inflation lumen;
a stopper means being sealingly affixed between the outer diameter of the guidewire shaft and the inner diameter of the distal tail, the stopper means being annular in shape and being in length shorter than the distal tail and being of uniform circumferential thickness; and
an adhesive sealing a portion of the distal tail, which is distal to the stopper means, to the catheter shaft.

Preferred embodiments of the invention will now be described by way of example only, with reference to the accompanying drawings.

FIG. 1 is a longitudinal cross section of the proximal end of the balloon of the present invention; and
FIG. 2 is a longitudinal cross-section of the distal end of the balloon.

The present invention provides a catheter balloon proximal or distal bond stopper which minimizes bond length while reliably withstanding internal pressures of at least 3.4MPa (500 psi) pressure without leaking or rupturing and which is relatively easy, consistent and reliable to manufacture. Figures 1 - 2 are longitudinal cross-sectional views of a high pressure balloon catheter adapted for use in percutaneous transluminal coronary angioplasty (PTCA). Fig. 1 represents the proximal bond stopper 30. Fig. 2 represents the distal bond stopper 50.

The proximal and distal bonds set forth herein were designed to solve problems resulting from the bonding of coaxial shafts. The bonds centre the two shafts which results in a uniform concentric alignment. The "positive stop" provided by a stopper is important to obtain a uniform gap into which adhesive can be dispensed. The invention also serves to stop the flow of adhesive past a defined point which is critical in balloon bonding since the presence of adhesive in the balloon/shaft area can adversely affect balloon in/deflation and balloon burst strength. A setback between the stopper and the end of the balloon cone increases the burst strength of the balloon and is necessary for high pressure balloons.

Since most catheter concentric proximal bonds of coaxial shafts have bond gaps of less than 0.125mm (.005 inches) between the distal end of the catheter shaft and the proximal end of the balloon tail, thin, low viscosity adhesives are typically used. The thinner the adhesive, the more important the use of the bonding stopper. With the present proximal bonding stopper 30 and distal bonding stopper 50, the bond length is controllable and therefore repeatable and more reliable. Without a uniform bond, the adhesive may flow past the desired bond length and may result in a blocked shaft and in/deflation problems.

The balloon 35 seen in Fig. 1 comprises shaft tubing 80 made of 50% HDPE / 50% LDPE, a coaxial inner guidewire shaft 70 made of HDPE defining a guidewire lumen 65 and a balloon 35 made of any material suitable for high pressures above 1.2×10^6 (12 atm) such as PET, PET blends or Nylon. The balloon 35 necks are trimmed to between approximately 1.5 mm to 4.0 mm at the proximal and distal ends. Bonding surfaces may be plasma treated to facilitate bonding.

To prevent adhesive leakage into the balloon 35 a proximal bond stopper 30 and/or a distal bond stopper 50 may be used. The stoppers 30, 50 form a slight interference fit with the balloon 35 and can be made from any conventional adhesive suitable for balloon bonding, or from any conventional radiopaque materials or from any heat shrinkable materials. The bond stoppers 30 or 50 can also be made by using a preform.

The dimensions of the stoppers 30, 50 whether they be radiopaque, heat shrinkable, adhesive or preform, will depend on the size of the catheter shaft 80 outer diameter, the guidewire shaft 70 outer diameter and the proximal balloon cone proximal end 55 and the distal balloon cone distal end 60 inner diameters. The difference between the proximal balloon cone proximal end 55 inner diameter and the catheter shaft 80 outer diameter gives the approximate thickness of the proximal bond stopper 30. The difference between the distal balloon cone distal end 60 inner diameter and the guidewire shaft 70 outer diameter gives the approximate thickness of the distal stopper 50. A typical stopper 30, 50 will range in thickness between 0.075mm and 0.225mm (.003 inches and .009 inches). Typically the LDPE shaft 80 which defines the inflation lumen 25 has a outer diameter of 0.8875mm (.0355 inches) and an inner diameter of 0.7mm (.028 inches). The guidewire shaft 70 typically has an outer diameter of 0.575mm (.023 inches) and an inner diameter of 0.425mm (.017 inches) to accommodate 0.35mm (.014 inch) guidewires.

Stoppers 30, 50 for catheters using conventional 0.35mm (.014 inch) guidewires are created as follows. A 0.75mm (0.030 inch) mandrel is loaded into the distal end of shaft 80 for support during stopper bonding. The proximal bond stopper 30 is located over the distal end

of the shaft 80 anywhere from flush with the distal end of shaft 80 to a proximal bond setback 15 of approximately .25 mm to .5 mm. The setback 15 increases the burst strength of the balloon and is preferable for high pressure balloons. The distal end of the guidewire shaft 70 is inserted into the shaft tubing 80 such that the distal end of the guidewire shaft 70 extends beyond the distal end of the shaft tubing 80. The distal end of the shaft 80 should align with the proximal end of the proximal balloon cone 55. The distal bond stopper 50 is located over the distal end of the guidewire shaft 70 anywhere from flush with the distal end of shaft 70 to a distal bond setback 45 of approximately 0.25 mm to 0.5 mm. The distal bond setback 45 increases the burst strength of the balloon and is preferable for high pressure balloons. A variety of catheter tip configurations may be used with the distal bond stopper 50.

The setback 15 or 45 is advantageous because it is reduces the difference in thickness, hardness or stiffness between the relatively stiff high pressure balloon 35 material and the relatively soft PE shaft 80. Abrupt changes in transition result in areas where kinking is likely. Additionally, bond strength is improved because the setback 15, 45 provides a longer "lever" or effective cone angle. The longer the setback 15, 45, and the longer the balloon cone angle, the less will be the peel force of the balloon neck separating from the shaft when under high pressure. Using a proximal bond setback 15 is more important than using a distal bond setback 45 as the proximal bond typically bursts before the distal bond does. This is because typically the proximal balloon neck wall thickness is thinner than the distal neck wall thickness and therefore is not as strong. The difference in wall thickness results from the proximal balloon neck inner diameter being typically larger than the distal neck inner diameter. Typically the proximal balloon neck is sized to fit the catheter guidewire shaft and inflation shaft whereas the distal balloon neck is sized to fit only the guidewire shaft. When the balloon is formed this difference in diameter results in wall thickness difference. The distal bond setback 45 is also less critical than the proximal bond setback 15 since for geometry reasons it is advantageous to eliminate anything that is unnecessary in the distal tip region so as to reduce tip length and profile.

If a heat shrinkable material is used for stoppers 30, 50 such as PE, the stoppers 30, 50 are heat shrunk using any conventional means. Adhesive stoppers may be less preferred than heat shrinkable stoppers if the adhesive viscosity is such that it creates the potential for adhesive migration before the adhesive dries. To reduce the likelihood of adhesive migration, adhesives with a viscosity which approaches a gel are preferred. If radiopaque materials such as platinum, iridium, gold, gold plated metal or combinations thereof, are used for stoppers 30, 50 they can be adhesively bonded to the catheter shaft 80 and to the guidewire shaft 70 respectively by using conventional cyannoacrylates as described below. The advantage of radiopaque stoppers is that the physician can flouroscopically view the progress of the balloon.

To create adhesive stoppers a fast curing adhesive such as cyanoacrylate e.g., Loctite® 4061, a medical grade adhesive manufactured by Loctite Corp. in Hartford CT is used. The preferred adhesive would require only one application and would be cured instantly. Loctite® 447 (600 cP) is suitable for forming the stopper in one application. Other possible Loctite® adhesives include 454 (gel), 4981 (700 cP), 4161 (1500 cP), 3091 (6000 cP), 3321 (5000 cP), 3211 (1000 cP). Dymax ® Corporation of 51 Greenwoods Rd., Torrington, CT has ultraviolet (UV) adhesives which may also be suitable.

The adhesive stoppers 30, 50 could be created using a conventional means such as a rotating fixture. Adhesive will be dispensed onto the catheter shaft 80 or onto the guidewire shaft 70 which is rotated through 360 degrees to create a complete uniform ring of adhesive approximately 0.5 mm wide. Create an adhesive stopper 30, 50 on the shaft tubing 80 or guidewire shaft 70 respectively which is approximately 0.002 mm high around the circumference. It is important for the shaft 70, 80 to continue rotating several seconds after dispensing the adhesive to ensure uniform application until the adhesive reaches "fixture-cure" or "complete-cure" and is dry. If UV adhesive is used, activate the ultraviolet light source.

To create a preform stopper 30, 50 one could use a radiopaque marker band which is preformed to a desired dimension or a polymer or elastomer o-ring or band that is premolded or extruded to the desired dimension.

Regardless of the stopper material used (heat shrinkable, radiopaque, adhesive or preform), the following applies. The stoppers 30, 50 should be trimmed to a length of approximately .5 mm plus or minus .25 mm. The distal 1.5 mm of the balloon proximal tail is placed over the distal end of the distal shaft tubing 80. The proximal bond 5 area proximal to the proximal bond stopper 30 is filled with enough adhesive to fill the 0.05mm - 0.075mm (0.002 -0.003 inch) gap between the proximal end of the proximal stopper 30 and the proximal end of the balloon proximal tail 75. UR-0531 or UR-2187 can be used and is available from H.B. Fuller of St. Paul, Minnesota. The distal 1.5 mm of the balloon distal tail 85 is placed over the distal end of the guidewire shaft tubing 70. The distal bond 10 area proximal to the distal bond stopper 50 is filled with enough adhesive to fill the 0.05mm - 0.075mm (0.002 - 0.003 inch) gap between the proximal end of the distal stopper 50 and the proximal end of the balloon distal tail 85. UR-0531 or UR-2187 can be used available from H.B. Fuller of St. Paul, Minnesota. More adhesive (such as UR-0531 or UR-2187 available from H. B. Fuller) is added to form a proximal bond adhesive fillet 40 and a distal bond fillet 20 which is from about .75 mm long to about 1 mm long. The fillets 20 and 40 taper down to the distal end of the

guidewire shaft 70 and down to the shaft tubing 80 respectively.

The preceding specific embodiments are illustrative of the practice of the invention. It is to be understood, however, that other expedients known to those skilled in the art or disclosed herein, may be employed without departing from the appended claims.

Claims

1. A medical catheter comprising:

   a catheter shaft (80) defining an inflation lumen (25), the catheter shaft having an inner diameter, outer diameter, proximal end and distal end;
   a guidewire shaft (70) defining a guidewire lumen (65), the guidewire shaft being coaxial with the catheter shaft, the guidewire shaft running longitudinally through the catheter shaft and extending distally beyond the distal end of the catheter shaft;
   an inflatable balloon (35) having a proximal tail having an inner diameter, a distal tail having an inner diameter, the proximal tail being mounted on to the distal end of the catheter shaft (80), the distal tail being mounted on to the guidewire shaft (70), the balloon being in fluid communication with the inflation lumen (25);
   a stopper means (30) sealingly affixed between the outer diameter of the catheter shaft and the inner diameter of the proximal tail, the stopper means being annular in shape and being in length shorter than the proximal tail and being of uniform circumferential thickness; and
   an adhesive sealing a portion (5) of the proximal tail, which is proximal to the stopper means, to the catheter shaft.

2. The medical catheter of claim 1 wherein the stopper means (30) is set back (15) proximally of the proximal end of the proximal cone by at least approximately 0.25 mm.

3. The medical catheter of claim 1 or 2 also comprises a proximal fillet (40) made from an adhesive material placed at the proximal end of the proximal balloon tail, the proximal fillet tapering down from the proximal tail to the catheter shaft.

4. A medical catheter comprising:

   a catheter shaft (80) defining an inflation lumen (25), the catheter shaft having an inner diameter, outer diameter, proximal end and distal end;
   a guidewire shaft (70) defining a guidewire lumen (65), the guidewire shaft being coaxial with the catheter shaft, the guidewire shaft running longitudinally through the catheter shaft and extending distally beyond the distal end of the catheter shaft;
   an inflatable balloon (35) having a proximal tail having an inner diameter, a distal tail having an inner diameter, the proximal tail being mounted at the distal end of the catheter shaft (80), the distal tail being mounted on the guidewire shaft (70), the balloon being in fluid communication with the inflation lumen (25);
   a stopper means (50) being sealingly affixed between the outer diameter of the guidewire shaft and the inner diameter of the distal tail, the stopper means being annular in shape and being in length shorter than the distal tail and being of uniform circumferential thickness; and
   an adhesive sealing a portion (10) of the distal tail, which is distal to the stopper means, to the catheter shaft.

5. The medical catheter of claim 4 wherein the stopper means (50) is set back distally of the distal end of the distal cone by at least approximately 0.25 mm.

6. The medical catheter of claim 5 or 6 wherein a distal fillet (20) of adhesive material is placed at the distal end of the distal balloon tail, the distal fillet tapering down from the distal tail to the guidewire shaft.

7. The medical catheter of any preceding claim wherein the stopper means (30,50) is made from an adhesive material.

8. The medical catheter of any of claims 1 to 3 wherein the stopper means (30,50) is made from a heat shrinkable material.

9. The medical catheter of any of claims 1 to 3 wherein the stopper means (30,50) is made from a radiopaque material.

10. The medical catheter of any preceding claim wherein the stopper means (30,50) is not more than approximately 0.75 mm in length.

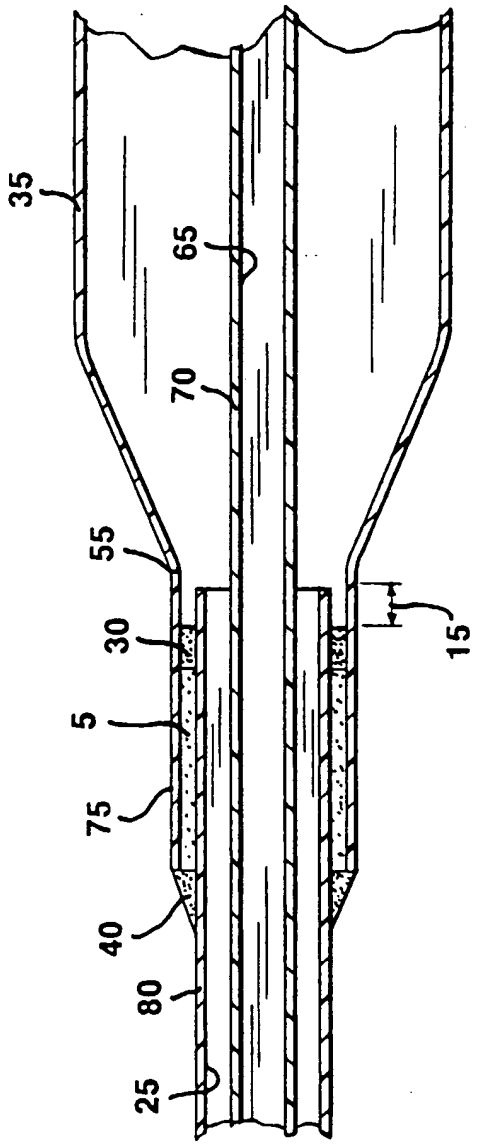

FIG.1

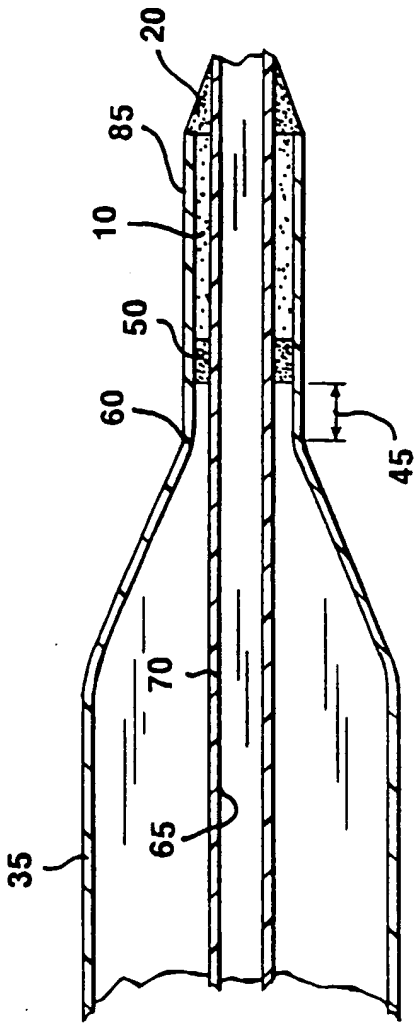

FIG.2

European Patent Office

EUROPEAN SEARCH REPORT

Application Number
EP 97 30 9826

DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int.Cl.6)
Y	EP 0 512 359 A (MINISTERO DELL UNIVERSITA E DELLA RICERCA SCIENTIFICA E TECNOLOGICA) * abstract * * page 5, line 30 - line 34 * * page 9, line 25 - line 29; figures 2-5 *	1-10	A61M25/10
Y	EP 0 540 858 A (ADVANCED CARDIOVASCULAR SYSTEMS, INC.) * abstract * * column 9, line 6 - line 15; figures 1-4 *	1-10	
A	US 5 569 201 A (BURNS)		

TECHNICAL FIELDS SEARCHED (Int.Cl.6)

A61M

The present search report has been drawn up for all claims

Place of search	Date of completion of the search	Examiner
THE HAGUE	13 March 1998	Michels, N

CATEGORY OF CITED DOCUMENTS

X : particularly relevant if taken alone
Y : particularly relevant if combined with another document of the same category
A : technological background
O : non-written disclosure
P : intermediate document

T : theory or principle underlying the invention
E : earlier patent document, but published on, or after the filing date
D : document cited in the application
L : document cited for other reasons

& : member of the same patent family, corresponding document

EPO FORM 1503 03.82 (P04C01)